

## REMARKS

The subject application includes claims 72-248. An Office Communication mailed on December 16, 2005 indicated that the Applicant's submission of new claims 136-248 failed to include arguments pointing out specific distinctions believed to render the claims patentable over any applied patent references, and where support for the new claims 136-248 is found in the specification. Specifically, the Office Communication stated the following:

“The reply must present arguments pointing out specific distinctions believed to render the claims, including any *newly* presented claims (newly added claims 136-248), and where support for the amendments is found in the specification and how they are patentable over any applied references” (emphasis in original).

Citations to MPEP §§ 714.02 and 2163.06 and 37 CFR §1.111 were made in reference to the quoted language.

The Applicant filed a Response to the Office Communication on January 17, 2006 in which the Applicant pointed out distinctions that are believed to render claims 136-248 patentable over any of the applied references, and also pointed out support for claims 136-248 in the specification.

However, on April 14, 2006, the Applicant received a further communication from the Examiner indicating that the response filed on January 17, 2006 was not fully responsive to the prior Office Communication, asserting that the “Applicants response does not point out the patentable novelty which the applicant believes the claims present in view of the state of the art disclosed by the references cited or the objections made [and] fails to point out where support is found in the (sic) disclosure.”

The Applicant has reviewed and considered the Office Communications and maintains that the prior Response filed on January 17, 2006 was fully responsive to the Office Communication mailed on December 16, 2005. Nevertheless, in view of the fact that Examiner Gherbi appears to be on extended leave and is unavailable to further clarify how the Applicant's previous response was insufficient and what additional information might be required to satisfy MPEP §§ 714.02 and 2163.06 and 37 CFR §1.111, the Applicant has chosen to cancel claims 136-248 from the subject application without prejudice for possible submission at a future date.

With regard to pending claims 72-134, in the Response filed with an RCE on September 14, 2005, the Applicant presented detailed arguments which addressed each and every rejection and objection set forth in the final Office Action. Specifically, the Applicant addressed the objection to the specification under 35 USC §132, the objection to claims 72-134 under 35 USC §112, first paragraph, and the rejection of claims 72, 91 and 111 under 35 USC §102(e). The Applicant notes that claims 72, 91 and 111 were the only claims that were rejected based on the teachings of a single prior art reference (U.S. Patent No. 6,371,988 to Pafford et al.).

With regard to independent claim 135, in the Response filed on September 14, 2005, the Applicant noted that claim 135 was is similar in scope to independent claim 72. Additionally, the Applicant pointed out the following differences between independent claim 135 and independent claim 72. Independent claim 135 recites “said upper and lower portions being flattened along at least a portion of the length of said implant”, whereas independent claim 72 recites “said upper and lower portions being non-arcuate along at least a portion of the length of said implant”. Further, independent claims 135 recites “an interior facing side and an exterior facing side opposite said interior side, said interior and exterior facing sides connecting said upper and lower portions and said leading and trailing ends, said leading end having a generally straight portion from side to side, said interior side forming a corner with said generally straight portion of said leading end, said interior side adapted to be oriented toward an interior side of another implant when inserted within the disc space”. Independent claim 72 recites similar language, with the additional recitation of “a maximum width” between the interior and exterior facing sides, with “said maximum width of said implant being less than approximately one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted”.

U.S. Patent No. 6,371,988 to Pafford et al. was the only patent reference asserted against the pending claims in the final Office Action, and assertion of the ‘988 patent was limited to independent claims 72, 91 and 111. The Applicant submits that independent claim 135 is patentable over the ‘988 patent for at least the following reasons.

Paragraph 6 of the final Office Action asserts that the ‘988 patent discloses an implant 40 having opposed upper and lower portions that are non-arcuate along at least a portion of

the length of the implant. The non-arcuate upper portion is asserted to constitute the beveled surface (shown in Figures 47 and 48) and the non-arcuate lower portion is asserted to constitute the crest 44 of the tooth 43 (shown in Figure 8). Albeit that the '988 patent discloses that "the crest 44 of each tooth 43 is flat" (column 7, line 65), this description appears to be referring to the appearance of the crest 44 in axial cross-section (as shown in Figure 8) wherein the crest 44 may be considered "flat" in a circumferential sense (i.e., in that the crest 44 extending circumferentially about the implant does not have a pointed configuration as is typically the case with bone threads). However, such a "flat" crest 44 extending along the circumference of the implant would not be flattened along the length of the implant. In other words, when viewed from either end of the implant (or via a transverse cross section), the crest 44 would still have a circular or arcuate configuration. Accordingly, the "flat" crest 44 described in the '988 patent specification would not define upper and lower portions that are flattened along the length of the implant, as recited in independent claim 135.

Moreover, the beveled surface shown in Figures 47 and 48 is referred to in the final Office Action as comprising a non-arcuate upper portion. However, the Applicant respectfully disagrees with this assertion in that the beveled surface does not comprise an upper portion of the implant "to contact and support" an adjacent vertebral body, as recited in independent claim 135. Specifically, the opening or chamber 25 extending through the implant (as shown in Figures 7, 47 and 48) contains an osteogenic composition and opens onto the upper and lower surfaces of the implant to promote bone growth from the endplates of the respective vertebral bodies and into the chamber 25. (See column 7, lines 50-56). Thus, one of ordinary skill in the art would understand that when the implants are positioned in the disc space, the chamber 25 opens onto the upper and lower surfaces of the implant adjacent the respective vertebral bodies. As a result, the portions of the implant that define the openings of the chamber 25 correspond to the "upper and lower portions" of the implant, and do not correspond to the portion of the implant defining the beveled surface. Indeed, the beveled surface is positioned along lateral or side portions of the implant, which would correspond to the interior or exterior facing side of the implant recited in independent claim 135. Accordingly, even assuming that the beveled surface comprises a flattened portion of the implant, the beveled surface does not comprise an upper or lower portion of the implant.

In addition to the above-discussed reasons, further reasons support the patentability of independent claim 135 over the '988 patent. For example, independent claim 135 recites that the implant is manufactured from a bone ring obtained from a major long bone having a medullary canal, with "said interior side of said implant including at least a portion of the medullary canal so that when said implant is placed side by side with another implant having an interior side including at least a portion of a medullary canal a passage is formed", with the passage adapted to hold bone growth promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is clearly illustrated in Figure 6 of the subject application wherein the interior facing sides 535 include at least a portion of the medullary canal so as to define facing chambers 530 of the bilaterally positioned implants 500 to form an elongated compartment 540 that can be filled with an osteogenic composition M. (See paragraph 66).

However, as shown in Figure 24 of the '988 patent, although the implants are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants (i.e., the sides of the implants which face one another) clearly do not include at least a portion of a medullary canal, as recited in independent claim 135. Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants. Since the interior sides of the implants do not include "at least a portion of the medullary canal", the '988 patent does not disclose each and every feature recited in independent claim 135. Accordingly, the '988 patent does not anticipate independent claim 135. Moreover, the chambers 25 extending through the implants illustrated in Figure 24 of the '988 patent do not form a common passage that is adapted to hold bone growth promoting material. To the contrary, the chambers 25 form separate and discrete passages extending through the implants. Accordingly, for at least these reasons, the Applicant submits that independent claim 135 is patentable over the teachings of the '988 patent.

As indicated above, independent claim 135 recites language similar to that recited in independent claim 72. Moreover, the Applicant submits that independent claim 135 is supported by the specification by at least the following portions of the specification and the drawing figures:

“An interbody spinal implant (page 9, lines 29-30) made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect (page 10, lines 18-19, Fig. 6, original claim 7)”;

“a leading end for insertion first into the disc space, a trailing end opposite said leading end (page 9, lines 30-31, Figs. 4-6 and 12), said implant having a length along a mid-longitudinal axis of said implant from said leading end to said trailing end (page 11, lines 29-30, Figs. 4, 6 and 12)”;

“opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in part within and across the height of the disc space to contact and support the adjacent vertebral bodies, said upper and lower portions being flattened along at least a portion of the length of said implant (page 14, lines 13-16)”;

“an interior facing side and an exterior facing side opposite said interior side (Fig. 6, reference numbers 500 and 535, Figs. 8-10 and 14), said interior and exterior facing sides connecting said upper and lower portions and said leading and trailing ends, said leading end having a generally straight portion from side to side (flat end surfaces shown in Figs. 6, 8-10 and 14), said interior side forming a corner with said generally straight portion of said leading end (corners formed between the interior surfaces and the end surfaces shown in Figs. 6, 8-10 and 14), said interior side adapted to be oriented toward an interior side of another implant when inserted within the disc space (as shown in Figs. 6, 8 and 9)”;

“said implant being manufactured from a bone ring obtained from a major long bone of a human having a medullary canal (page 9, lines 21-26; original claim 10), said interior side of said implant including at least a portion of the medullary canal so that when said implant is placed side by side another implant having an interior side including at least a portion of a medullary canal a passage is formed adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through said passage (page 10, lines 16-25, page 10, line 31 to page 11, line 6, Figs. 6, 8 and 9)”.

Based on the forgoing amendments and remarks, reconsideration and allowance of the subject application, including pending claims 72-135, are hereby requested.

### CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that Applicant's application is now in condition for allowance with pending claims 72-135.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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